

REMARKS

Claims 1-12 are pending in the application and have been examined. Claims 1-12 stand rejected. Reconsideration and allowance of Claims 1-12 are respectfully requested.

Interview Summary

Applicants and applicants' attorney acknowledge with appreciation the Examiner's courtesy of granting a telephone interview with applicants' attorney on November 4, 2004. The following is a summary of the interview.

The rejection of the pending claims under 35 U.S.C. § 103(a) as obvious over WO 95/20313 (Osorio et al.) over Alvarez-Ortega et al. (1997) *Lipids* 32(8):833-7 was discussed. Applicants' attorney pointed out that neither Osorio et al. nor Alvarez-Ortega et al. disclose or suggest a sunflower line having *both* an oleic acid content *above* 40% and a stearic acid content *above* 12%. No agreement was reached.

The Rejection of Claims for Nonstatutory Double Patenting

The Examiner has rejected Claims 6-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-6 of U.S. Patent No. 6,388,113, over Claims 1, 4, 7, and 11 of U.S. Patent No. 6,348,610, and over Claims 1, 7-8, 11, and 12 of U.S. Patent No. 6,486,336. A terminal disclaimer over U.S. Patent No. 6,388,113, U.S. Patent No. 6,388,113, and U.S. Patent No. 6,486,336 is enclosed. Applicants respectfully request withdrawal of this ground of rejection.

The Rejection of Claims Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 1-12 under 35 U.S.C. § 103(a) as obvious over WO 95/20313 (Osorio et al.) over Alvarez-Ortega et al. (1997) *Lipids* 32(8):833-7. According to the Examiner, Osorio et al. discloses a sunflower oil comprising between 3-85% oleic acid and 10-19%, 19.1-35%, or 29-54% stearic acid. Also according to the Examiner, Alvarez-Ortega

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et al. discloses that the amounts of the saturated fatty acid in position 2 of triacylglycerol of the sunflower mutants described in Osorio et al. are less than 10%. The Examiner therefore indicates that it would have been obvious to use sunflower oil compositions comprising more than 40% oleic acid and more than 12% stearic acid, wherein a maximum of 10% of the fatty acid groups are in the sn-2 position of triacylglycerol, in a food product or a cosmetic product. Applicants respectfully disagree.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. There are three requirements for establishing a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in knowledge generally available to one of ordinary skill in the art, to modify the reference. The Second, there must be a reasonable expectation of success. As was stated by the predecessor court to the Federal Circuit, "[w]e must not here consider a reference in a vacuum but against the background of the other references of record which may disprove theories and speculations in the reference, or reveal previously undiscovered or unappreciated problems." *In re Ehrreich*, 200 U.S.P.Q. 504, 509-10 (C.C.P.A. 1979). Third, the prior art reference must teach or suggest all the claim limitations.

Applicants submit that there is no suggestion or motivation, either in Osorio et al. or in Alvarez-Ortega et al., or in knowledge generally available to one of ordinary skill in the art, to prepare a food or cosmetic product comprising an oil having an oleic acid content of more than 40% and a stearic acid content of more than 12%. Although Osorio et al. separately claims a sunflower oil comprising between 3-85% oleic acid (Osorio et al., Claim 8) and 10-19% (Osorio et al., Claim 4), 19.1-35% (Osorio et al., Claim 2), or 29-54% stearic acid (Osorio et al., Claim 7), it neither discloses nor suggests a sunflower line having *both* an oleic acid content *above* 40% and a stearic acid content *above* 12%. In fact, it only discloses sunflower oil having a stearic

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acid content, such as mutant lines CAS-3 and CAS-4. Specifically, oil from mutant line CAS-3 was determined to contain 26% stearic acid and 13.8% oleic acid, and oil from mutant line CAS-4 was determined to contain 16.1% stearic acid and 24.3% oleic acid for CAS-4 (Osorio et al., page 9, lines 31-32; Specification, page 20, lines 20-21). None of the sunflower oils disclosed in Osorio have an oleic acid content above 40%.

Alvarez-Ortega et al. discloses the fatty acid composition of seed lipids from high stearic acid mutants such as CAS-3 and CAS-4. As shown in Table 1 of Alvarez-Ortega et al., the total stearic acid content of oils from the high stearic acid mutants disclosed in Alvarez-Ortega et al. ranges from 11.7% to 26.1% (Alvarez-Ortega et al., page 834, Table 1). The total stearic acid content of oils from all the other lines analyzed in Alvarez-Ortega et al. is well below 12% (ranging from 1.7% to 4.9%). The total oleic acid content in the oils from the high stearic acid mutants disclosed in Alvarez-Ortega ranges from 14.2% to 27.8% (Alvarez-Ortega et al., page 834, Table 1). Therefore, Alvarez-Ortega et al. neither discloses nor suggests a sunflower line having *both* an oleic acid content *above 40%* and a stearic acid content *above 12%*, as recited in Claims 1-12.

Moreover, there is no reasonable expectation of success at arriving at the claimed invention by combining the teachings of Osorio et al. and Alvarez-Ortega et al. Although Osorio et al. states that oil having an oleic acid content between 2 and 84% may be obtained by crossing the high stearic acid lines of Osorio et al. with lines "having a desirable content of one or more unsaturated and/or saturated fatty acids" (Osorio et al., page 5, lines 1-9), the inventors have shown that crossing high stearic acid lines with high oleic acid lines did not result in lines having both high stearic acid and high oleic acid content. As stated in parent Application No. 09/326,501, which issued as U.S. Patent No. 6,388,113:

Originally it was believed that crossing the prior art high oleic lines with the prior art high stearic lines would produce an inbred line having high oleic and high stearic

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properties. Unfortunately, this has proved extremely difficult. The prior art high stearic acid content lines, which were selected after mutagenesis, like CAS-3, evidenced low oleic content. Likewise, most oleic varieties evidenced low stearic acid content.

We have discovered that the selection process for very high oleic material, particularly in sunflower, selects against stearic acid generally (U.S. Patent No. 6,388,133, col. 8, lines 54-64).

Thus, it was found that "[t]he fatty acid pathway in most oilseed plants appears to be resistant to maintaining both oleic and stearic at elevated levels" (Specification, page 4, lines 24-26). As mentioned above, *In re Ehrreich* points out that a reference must not be considered in a vacuum, and that other references of record that "may disprove theories and speculations in the reference, or reveal previously undiscovered or unappreciated problems" must also be considered. *In re Ehrreich*, 200 U.S.P.Q. at 509-10.

The present invention is based on the surprising finding that crossing a sunflower line with a high stearic acid content, such as CAS-3 or CAS-4, with a sunflower line with a high oleic acid content *and high thioesterase activity* results in seeds containing an oil having both a high stearic acid content (such as more than 12%) and a high oleic acid content (such as more than 40%), in which a maximum of 10% of the fatty groups in the sn-2 position of triacylglycerol molecules are saturated fatty acid groups (Specification, page 6, lines 23-33). As stated in the parent application:

The reason a [high oleic acid and high thioesterase] line is necessary and the high oleic acid trait does not appear to be sufficient is that it [has] been found that the selection process for very high oleic material selects against stearic generally and also against elevated thioesterase activity over the stearyl-ACP (U.S. Patent No. 6,388,133, col. 10, lines 30-35).

Applicants submit that there is no suggestion or motivation, either in Osorio et al. or in Alvarez-Ortega et al., or in knowledge generally available to one of ordinary skill in the art, to prepare a food or cosmetic product comprising an oil having an oleic acid content of more than 40% and a stearic acid content of more than 12% by crossing a high stearic acid line with a high

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oleic acid and high thioesterase line. Instead, Osorio et al. teaches away from the claimed invention by suggesting that tailor-made oil having high stearic acid content and a desirable content of one or more unsaturated and/or saturated fatty acids (such as high oleic acid content) can be obtained simply by crossing mutant stearic acid lines, such as CAS-3 and CAS-4, with lines with seeds having the desired content of these other fatty acids (Osorio et al., page 5, lines 5-9). However, applicants have shown that such an approach is not feasible, as described above. In order to obtain a sunflower oil having both high stearic acid and high oleic acid content, it was necessary to cross a sunflower line with a high stearic acid content with a sunflower line having *not only* high oleic acid content *but also high thioesterase activity*. Therefore, there is no reasonable expectation of success of arriving at the claimed invention by combining the teachings of Osorio et al. and Alvarez-Ortega et al.

Thus, neither Osorio et al. nor Alvarez-Ortega et al. teaches, suggests, or provides any reasonable expectation of success of obtaining an oil containing more than 40% oleic acid and more than 12% stearic acid, as recited in Claims 1-12. For these reasons, applicants respectfully request withdrawal of this ground of rejection.

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## CONCLUSION

In view of the foregoing amendments and remarks, Claims 1-12 are believed to be in condition for allowance. If any issues remain that can be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at 206.695.1783.

Respectfully submitted,

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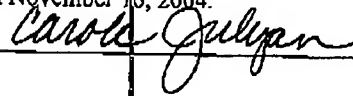


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